



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,387	11/22/2005	Timo Hillebrand	050372	2884
7590 Buchanan Ingersoll One Oxford Centre 301 Grant St., 20th Floor Pittsburgh, PA 15219		01/15/2008	EXAMINER STAPLES, MARK	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 01/15/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,387

Applicant(s)

HILLEBRAND ET AL.

Examiner

Mark Staples

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-40, 44-47, 49-52 and 57-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-40, 44-47, 49-52 and 57-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2007 has been entered.

Applicant's amendment of claims 35, 36, 58, and 59 in the paper filed on 10/19/2007 is acknowledged. Claims 1-34, 41-43, 48, and 53-56 have been cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 35-40, 44-47, 49-52, and 57-59 are pending and at issue.

Rejections that are Withdrawn / Moot

Claim Rejections Withdrawn - 35 USC § 112 second paragraph

2. The rejections of claims 35-47, 49-52, 57, and 59 under 35 U.S.C. 112, second paragraph are withdrawn as Applicant's amendments to the claims have overcome these rejections.

Claim Rejections Withdrawn - 35 USC § 102

3. The rejection of claim 35-40, 44-47, 49, 50, 52, 58, and 59 under 35 U.S.C. 102(b) as being anticipated by Smith et al. (US Patent 6,376,194) is withdrawn.

Applicant's arguments with respect to these claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections Withdrawn - 35 USC § 103

4. The rejection of claims 51 and 57 under 35 U.S.C. 103(a) as being unpatentable over Smith et al. as applied to claim 35 above, and further in view of Seed et al. (1994) is withdrawn.

Applicant's arguments with respect to these claims have been considered but are moot in view of the new ground(s) of rejection.

New Rejections

Claim Rejections - 35 USC § 112

5. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 52 recites the limitation "step (e)" in 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 35-40, 44-47, 49-52, and 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Ekenberg (United States Patent No. 6,218,531 issued April 17, 2001).

Regarding claims 35-38, 44-47, 50-52, and 57 Ekenberg teaches methods for isolating nucleic acids which are RNA and DNA from a solution by binding to a solid phase (entire patent) comprising the steps of:

- a. providing a solution containing at least one nucleic acid;
- b. combining said solution with additives containing non-chaotropic multivalent cations and non-chaotropic monovalent cations in combination by teaching an alternative aspect of isolating RNA by: " providing a binding mixture comprising RNA, DNA, and a binding enhancer, wherein the binding enhancer is selected from the group consisting of a non-chaotropic salt . . (see column 8 lines 21-27) and where the non-chaotropic multivalent cations are Mn^{2+} of $MnCl_2$ and the non-chaotropic monovalent cations are Na^+ of $NaCl$ (see column 6 line 32), and see claim 16 for a buffer with at least about 1 mM $MgCl_2$ and up to about 1 M $NaCl$ (which can be less than 5 mM), and so that a 9:1

monovalent to multivalent cation ratio is achieved with 9 mM NaCl and 1 mM MgCl₂ for a total 10 mM salt which is greater than 5 mM and less than 0.5 M;

c. optionally combining said solution with an alcohol (see column 8 lines 21-27);

d. providing a solid carrier which is a silica matrix (see column 8 line 30), wherein said solid carrier comprises at least one constituent selected from the group consisting of magnetic silica particles which are magnetic beads coated with silica and silica membranes which are silica impregnated or coated filters (see column 5 lines 38-55); contacting said solution with said carrier and binding said at least one nucleic acid to said carrier; and removing/eluting said nucleic acid from said carrier by a wash/elution buffer (see column line 49-53) which can be a tris solution of 10 mM Tris which can be pH 8.5 (see column 16 lines 48-65) and where this solution preferable comprises but need not comprise an alcohol (see column 15 line 60).

Regarding claims 39 and 49, Ekenberg teaches: "The alcohol in the mixture is preferably a low molecular weight alcohol, such as ethanol or isopropanol . . . " (column 14 lines 29-32).

Regarding claim 40, Ekenberg teaches RNA in Tris buffer (see column 23 lines 1-8).

Regarding claims 58 and 59, Ekenberg teaches kits/test products for isolating/purifying DNA (entire patent, especially column 4 lines 43-36) and teaches: lysis/binding buffers (see column 5 lines 1-4); wash and elution buffers (see column line 49-53) and;

non-chaotropic divalent cation Mn^{2+} of $MnCl_2$ and the non-chaotropic monovalent cation Na^+ of $NaCl$ (see column 6 line 32), and see claim 16 for a $MgCl_2$ with divalent Mg^{2+} and $NaCl$, for alcohol see column 8 lines 21-27, and for Tris for adjusting pH see column 16 lines 48-65;

solid carriers which are a silica matrix (see column 8 line 30), wherein said solid carrier comprises at least one constituent selected from the group consisting of magnetic silica particles which are magnetic beads coated with silica and silica membranes which are silica impregnated or coated filters (see column 5 lines 38-55).

Rejections that are Maintained

Specification

9. The objection to the disclosure is maintained for the following informalities: for using "PCT" in the 3rd sentence of paragraph 036, it appears "PCR" is intended.

Appropriate correction is required.

Conclusion

10. No claim is free of the prior art.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.


Application/Control Number:
10/534,387
Art Unit: 1637

Page 7

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples 
Examiner
Art Unit 1637
January 9, 2008


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

1/10/08